PPH Medicines and Devices Portfolio

Sara Rushwan, Concept Foundation, MHS Caucus, 17 October 2023
Country Support
Project title:
Accelerating access to essential medicines to reduce PPH morbidity and mortality

Policy updates:
National guidelines, EMLs and EPHS

Developing clinical protocols and job aids

Implementation pilots on safe and appropriate use

EML - Essential Medicines List
EPHS - Essential Packages of Health Services
Policy change objective:
Update national policies to include HSC and TXA
**Project Countries**
15 sub-Saharan African countries with a high burden of PPH

<table>
<thead>
<tr>
<th>East African Community</th>
<th>Economic Community of West African States</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Burundi</td>
<td>1. Burkina Faso</td>
</tr>
<tr>
<td>2. DRC</td>
<td>2. Ghana</td>
</tr>
<tr>
<td>3. Ethiopia</td>
<td>3. Ivory Coast</td>
</tr>
<tr>
<td>4. Rwanda</td>
<td>4. Liberia</td>
</tr>
<tr>
<td>5. South Sudan</td>
<td>5. Mali</td>
</tr>
<tr>
<td>6. Tanzania</td>
<td>6. Sierra Leone</td>
</tr>
<tr>
<td>7. Uganda</td>
<td>7. Senegal</td>
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<td>8. Zanzibar</td>
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</tbody>
</table>
**10 countries** updated their national guideline and/or EML to include HSC and TXA

Status of inclusion of heat-stable carbetocin and tranexamic acid into national guidelines and EMLs:

<table>
<thead>
<tr>
<th>Country</th>
<th>National guideline status</th>
<th>National EML status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Burkina Faso</td>
<td>Updated &amp; MOH approved</td>
<td>Updated &amp; MOH approved</td>
</tr>
<tr>
<td>2. DRC</td>
<td>Draft stage</td>
<td>Draft stage</td>
</tr>
<tr>
<td>2. Ethiopia</td>
<td>Draft stage</td>
<td>Draft stage</td>
</tr>
<tr>
<td>4. Ghana</td>
<td>Draft stage</td>
<td>Draft stage</td>
</tr>
<tr>
<td>5. Liberia</td>
<td>Updated &amp; MOH approved</td>
<td>Updated &amp; MOH approved</td>
</tr>
<tr>
<td>6. Rwanda</td>
<td>Updated &amp; MOH approved</td>
<td>Updated &amp; MOH approved</td>
</tr>
<tr>
<td>7. Senegal</td>
<td>Draft stage</td>
<td>Draft stage</td>
</tr>
<tr>
<td>8. South Sudan</td>
<td>Draft stage</td>
<td>Draft stage</td>
</tr>
<tr>
<td>9. Sierra Leone</td>
<td>Draft stage</td>
<td>Draft stage</td>
</tr>
<tr>
<td>10. Ivory Coast</td>
<td>Not updated</td>
<td>Not updated</td>
</tr>
<tr>
<td>11. Uganda</td>
<td>Updated &amp; MOH approved</td>
<td>Updated &amp; MOH approved</td>
</tr>
</tbody>
</table>

1Burundi, Mali, Tanzania, and Zanzibar did not progress in revising their national guideline and EML within the timeframe due to a range of contextual factors, including the recent update of national policies.
Challenges in updating national guidelines and essential medicines lists in Sub-Saharan African countries to include WHO-recommended postpartum hemorrhage medicines

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Updated Essential Packages of Health Services

Ghana

NATIONAL ESSENTIAL HEALTH SERVICES PACKAGE
GHANA
2022-2030

MINISTRY OF HEALTH
THE NATIONAL ESSENTIAL HEALTH CARE PACKAGE FOR UGANDA
OCTOBER 2022

Ministry of Health & Sanitation
Essential Health Services Package for UHC
Freetown, December 2022
Key learnings from policy change and clinical protocol development

❖ Political will and civil society engagement are key gateways to policy change

❖ Convening expert working groups that include representation from professional associations is integral to clinical protocol development and operationalization

❖ Success is sustainable when efforts are locally-driven

❖ There is added value to operationalizing global recommendations at the national level when OBGYN and midwifery associations work in partnership
Developing clinical PPH protocols and job aids

Outputs:

• 2 published joint FIGO and ICM statements on PPH prevention and treatment
• 8 Expert Working Groups
• Published generic PPH prevention and management protocol
• 5 newly developed national clinical PPH protocols
• 2 revised national PPH clinical protocols
• 41 Job Aids
• 1 IJGO PPH-specific Supplement
HSC and TXA implementation pilots

**Overall Study Objectives:**
1) To assess safe and appropriate use of HSC for PPH prevention, and TXA for PPH treatment, and 2) their integration into standard care.

**Study start and end date**

1st May - 31st December 2022

**Study Countries**

- Burkina Faso
- Ethiopia
- Ghana
- Sierra Leone
- Uganda
Study Design

**BASELINE**
Baseline data collection to from 1st May to 30th June 2022

**TRAINING**
Facility-level training of trainers and staff of all study facilities

**IMPLEMENTATION**
- Introduction of HSC and TXA into all study facilities (*medicines were supplied by IDA Foundation*)
- Post-intervention data collection for a 2-month period
- Principal investigators/assigned seniors carried out weekly monitoring and monthly support supervision of all study facilities
<table>
<thead>
<tr>
<th>Country</th>
<th>No. of deliveries captured in the study</th>
<th>No. of healthcare providers sampled for qualitative research</th>
<th>No. of BEmONCs</th>
<th>No. of CEmONCs</th>
<th>No. of healthcare providers trained on using HSC and TXA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burkina Faso</td>
<td>3617</td>
<td>30</td>
<td>2</td>
<td>2</td>
<td>102</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>3840</td>
<td>28</td>
<td>2</td>
<td>2</td>
<td>226</td>
</tr>
<tr>
<td>Ghana</td>
<td>4332</td>
<td>40</td>
<td>2</td>
<td>2</td>
<td>237</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>3361</td>
<td>26</td>
<td>2</td>
<td>2</td>
<td>175</td>
</tr>
<tr>
<td>Uganda</td>
<td>9966</td>
<td>16</td>
<td>1</td>
<td>2</td>
<td>221</td>
</tr>
<tr>
<td>TOTAL</td>
<td>25116</td>
<td>140</td>
<td>9</td>
<td>10</td>
<td>961</td>
</tr>
</tbody>
</table>
Quantitative results summary

- HSC was the **most used uterotonic** for PPH prevention in both BEmONCs and CEmONCs during implementation.

- HSC was administered in combination with other uterotonics to **3.1%** of women in Ghana, **0.5%** of women in Burkina Faso and Uganda, and **0.1%** in Sierra Leone (all in CEmONCs).

- Ampoule counts showed that HSC **was not used** for labour induction and augmentation at all study facilities.

- During implementation, times from delivery to TXA administration for PPH treatment in all study facilities were **within the 180-minute** WHO-recommended treatment time.

- **75%** of healthcare providers in all study countries visually estimate blood loss (N = 140).
Qualitative results summary

Healthcare providers overall did not have major hesitations over use of HSC and/or TXA

<table>
<thead>
<tr>
<th>THEME</th>
<th>SUB-THEME</th>
<th>EXAMPLE QUOTE/S</th>
<th>OCCURRENCE IN COUNTRIES</th>
<th>STUDY PHASE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hesitations using HSC/TXA</td>
<td>Reasons for hesitations</td>
<td>&quot;Lack of knowledge about the products&quot;</td>
<td>All countries</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;We don’t have the drugs and don’t know how to use them&quot;</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>&quot;Fear about the effectiveness of HSC&quot;</td>
<td>Ethiopia</td>
<td>Baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Lack of training and availability of the drugs&quot;</td>
<td>All countries</td>
<td>Baseline + Implementation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Deepening knowledge of thermostable carbetocin&quot;</td>
<td>Burkina Faso</td>
<td>Implementation</td>
</tr>
<tr>
<td></td>
<td></td>
<td>&quot;Further training on use of TXA because the administration time is long; the product requires great caution&quot;</td>
<td>Burkina Faso</td>
<td>Implementation</td>
</tr>
</tbody>
</table>
Learnings from the implementation pilots

- Healthcare providers had favorable opinions about both medications in terms of ease of use (no cold chain required) and perceived effectiveness at reducing PPH with no reported adverse events.

- HSC and TXA can be feasibly integrated into routine care but there is a need for a holistic approach to PPH training with supportive supervision.

- Impact of introducing HSC and TXA on established practices (such as combining oxytocin and misoprostol for PPH prevention) should be monitored.

- Health information systems need to be improved for reliable record capture of timing of administration.
Supplement on implementation research from 9 LMIC to be published in Q1 2024

Scope of supplement: Feasibility, acceptability and appropriate use of two WHO-recommended PPH medicines: heat-stable carbetocin and tranexamic acid
Research & Innovation
Project 2: Accelerating Innovation for Mothers (AIM)

**ACTIVITY 1**
Clinical trial capacity assessment and strengthening for an LMIC clinical trial network

**ACTIVITY 2**
Historical funding analysis of the R&D landscape for Maternal Health medicines

**ACTIVITY 3**
Maternal Health Pipeline

**ACTIVITY 4**
Target Product Profiles

**ACTIVITY 5**
Systematic and Scoping reviews

**ACTIVITY 6**
AIM-Gender
Impact

Stakeholder analysis

Maternal Health Pipeline

TPPs
Maternal Health Pipeline

Our mapping of the Maternal Health Pipeline 2000-2023 generated:

- 444 drugs candidates for five main pregnancy conditions
- 36 devices for PPH
- 216 diagnostics for PE/E, PTL/B and IUGR
- 70 medicines for maternal anaemia
• **36 devices** were identified as in use or investigated for PPH between 2000 and 2023

• Balloons dominate, but **novel approaches are emerging**

• Repurposed and **improvised devices** are the norm
TXA research and market shaping activities

We have a series of ongoing TXA research activities designed to establish the availability and quality of TXA products in high-burden LMIC:

• Quality studies of TXA and oxytocin – published and ongoing
• TXA compatibility studies – published and ongoing
• TXA manufacturer landscaping
• Regulatory status and availability in high-burden countries
• Assessments of TXA innovations
Project 3: Uterotonic Medication Quality: Contributions Toward Universal Health Coverage

• Key aims of the study are to:
  ❖ **Highlight the importance of safeguarding uterotonic medication quality** in low- and middle-income countries
  ❖ Generate evidence to drive policy change through demonstrating both the health and economic impact that substandard uterotonics could have

Key findings from Ghana and Nigeria models:

• Substandard uterotonic use contributes to **$89 million in total costs of care** annually in Nigeria
• Substandard uterotonic use contributes to **$18.8 million in total costs of care** annually in Ghana
Resources:

Access-PPH project:  https://www.conceptfoundation.org/pph/

AIM project:  https://www.conceptfoundation.org/accelerating-innovation-for-mothers/

IJGO supplement:  https://obgyn.onlinelibrary.wiley.com/toc/18793479/2022/158/S_1

THANK YOU!

https://www.conceptfoundation.org/

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